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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,548	10/18/2001	Dongfang Liu	M0656/7070(HCL)	7782

23628 7590 12/29/2005

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EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

15

Office Action Summary	Application No.	Applicant(s)	
	09/982,548	LIU ET AL.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3-5,11-31,33-38,42,43,58,59,73,79,82,89-91,99,113-125,127-139,158-160,162-170,176,177,185-198,200-218 and 220-222.* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date. _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,3-5,11-31,33-38,42,43,58,59,73,79,82,89-91,99,113-125,127-139,158-160,162-170,176,177,185-198,200-218 and 220-222.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 29, 2005 has been entered.

It is noted that due to the various claim amendments, all of the claims are no longer seen to encompass the same inventive concept. As such, due to the divergent scope of the various claims, a restriction requirement is necessary. It is noted that upon election of an invention, the examiner will discuss any previous rejections correlative to the elected group, and any of applicants arguments which were set forth in the August 29, 2005 communication.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-5, 11-31, 33-38, 42, 82, 89, 113-115, and 135-139, drawn to methods of producing a therapeutic effect by administering heparin-like glycosaminoglycan (HLGAG) particles having a diameter of 1-500 microns, classified in class 514, subclass 56.

II. Claims 43, 58, 116-121, and 204-214, drawn to unformulated HLGAG particles having a diameter of 1-500 microns and methods of using the same, classified in class 514, subclass 56.

III. Claims 59, 73, 79, 130-134, 158-160, 162-167, 170, and 176-177, drawn to methods of delivering a therapeutic polysaccharide, classified in class 514, subclass 56.

IV. Claim 90, drawn to a composition comprising an HLGAG with a tap density of greater than 0.4 g/cm^3, classified in class 514, subclass 56.

V. Claims 91 and 185-190, drawn to kits comprising HLGAG formulated to release at least 5% of the HLGAG within 2 hours, classified in class 514, subclass 56.

VI. Claims 99, 191-198, and 200-203, drawn to methods for delivering a polysaccharide by administering an unformulated glycosaminoglycan (GAG) and a formulated GAG, classified in class 514, subclass 56.

VII. Claims 122-129, 215-218, and 220-222, drawn to compositions comprising an unformulated HLGAG and a formulated glycosaminoglycan, classified in class 514, subclass 56.

VIII. Claims 168-169, drawn to methods of delivering a therapeutic polysaccharide by administering a HLGAG and an additional therapeutic agent, classified in class 514, subclass 56.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. The invention of group I is drawn to methods of producing therapeutic effects by administering an HLGAG particle having a diameter of 1-500 microns and the invention of group II is drawn to unformulated glycosaminoglycan or HLGAG

particles. It is noted that the methods of group I do not require the HLGAG to be formulated or unformulated, and thus a reference anticipating or rendering obvious group I would not necessarily anticipate or render obvious group II.

Inventions I and III are unrelated. The invention of group I is drawn to methods of producing therapeutic effects by administering an HLGAG particle having a diameter of 1-500 microns and the invention of group III is drawn to methods of delivering HLGAG to produce a peak plasma concentration within 2 hours. It is noted that the methods of group I require the HLGAG to have a diameter of 1-500 microns and the methods of group III have no size limitations, and thus a reference anticipating or rendering obvious group I would not necessarily anticipate or render obvious group III.

Inventions I and IV are unrelated. The invention of group I is drawn to methods of producing therapeutic effects by administering an HLGAG particle having a diameter of 1-500 microns and the invention of group IV is drawn to a HLGAG composition with particles having a tap density of greater than 0.4 g/cm^3. It is noted that the methods of group I do not require the specific tap density of group III and the compositions of group III do not require the particles to be of any size, and thus a reference anticipating or rendering obvious group I would not necessarily anticipate or render obvious group IV.

Inventions I and V are unrelated. The invention of group I is drawn to methods of producing therapeutic effects by administering an HLGAG particle having a diameter of 1-500 microns and the invention of group V is drawn to a kit comprising HLGAG formulated to release at least 5% of the HLGAG within 2 hours. It is noted that the methods of group I do not require the HLGAG to be released at any rate and the kits of group V do not require the particles to be of

a certain size, and thus a reference anticipating or rendering obvious group I would not necessarily anticipate or render obvious group V.

Inventions I and VI are unrelated. The invention of group I is drawn to methods of producing therapeutic effects by administering an HLGAG particle having a diameter of 1-500 microns and the invention of group VI is drawn to methods of delivering polysaccharides by administering an unformulated glycosaminoglycan and a formulated GAG. It is noted that the methods of group I do not require formulated and unformulated GAG's and the methods of group VI do not require a specific sized HLGAG, and thus a reference anticipating or rendering obvious group I would not necessarily anticipate or render obvious group VI.

Inventions I and VII are unrelated. The invention of group I is drawn to methods of producing therapeutic effects by administering an HLGAG particle having a diameter of 1-500 microns and the invention of group VII is drawn to compositions comprising an unformulated HLGAG and a formulated GAG. It is noted that the methods of group I do not require the HLGAG to be formulated or unformulated, and the compositions of group VII do not require a certain size particle, and thus a reference anticipating or rendering obvious group I would not necessarily anticipate or render obvious group VII.

Inventions I and VIII are unrelated. The invention of group I is drawn to methods of producing therapeutic effects by administering an HLGAG particle having a diameter of 1-500 microns and the invention of group VIII is drawn to methods of delivering HLGAG to produce a peak plasma concentration within 2 hours and further administering an additional therapeutic agent. It is noted that the methods of group I do not require an additional therapeutic agent and the methods of group VIII do not have the size limitations of group I, and thus a reference

anticipating or rendering obvious group I would not necessarily anticipate or render obvious group VIII.

Inventions II and III are unrelated. Invention II is drawn to an unformulated HLGAG with a diameter of 1-500 microns and the invention of group III is drawn to methods of delivering therapeutic polysaccharides. It is noted that the compositions of group II require the HLGAG to be unformulated wherein the methods of group III do not. Moreover, the compositions of group II require the HLGAG to have a diameter of 1-500 microns and the methods of group III have no size limitations, and thus a reference anticipating or rendering obvious group II would not necessarily anticipate or render obvious group III.

Inventions II and IV are unrelated. Invention II is drawn to an unformulated HLGAG with a diameter of 1-500 microns and the invention of group IV is drawn to a HLGAG composition with a tap density of 0.4 g/cm^3. It is noted that the compositions of group II require the HLGAG to be unformulated and have a diameter of 1-500 microns wherein the compositions of group IV requires a specific tap density, which is not required by group II, and thus a reference anticipating or rendering obvious group II would not necessarily anticipate or render obvious group IV.

Inventions II and V are unrelated. Invention II is drawn to an unformulated HLGAG with a diameter of 1-500 microns and the invention of group V is drawn to a kit comprising HLGAG formulated to release at least 5% of the HLGAG within 2 hours. It is noted that the compositions of group II do not require the HLGAG to be released at any rate and the kits of group V do not require the particles to be of a certain size, and thus a reference anticipating or rendering obvious group II would not necessarily anticipate or render obvious group V.

Inventions II and VI are unrelated. Invention II is drawn to an unformulated HLGAG with a diameter of 1-500 microns and the invention of group VI is drawn to methods of delivering polysaccharides by administering an unformulated glycosaminoglycan and a formulated GAG. It is noted that the methods of group I do not require formulated and unformulated GAG's and the methods of group VI do not require a specific sized HLGAG, and thus a reference anticipating or rendering obvious group II would not necessarily anticipate or render obvious group VI.

Inventions II and VII are unrelated. Invention II is drawn to an unformulated HLGAG with a diameter of 1-500 microns and the invention of group VII is drawn to compositions comprising an unformulated HLGAG and a formulated GAG. It is noted that the compositions of group I do not require the HLGAG to be formulated or unformulated, and the compositions of group VII do not require a certain size particle, and thus a reference anticipating or rendering obvious group II would not necessarily anticipate or render obvious group VII.

Inventions II and VIII are unrelated. Invention II is drawn to an unformulated HLGAG with a diameter of 1-500 microns and the invention of group VIII is drawn to methods of delivering HLGAG to produce a peak plasma concentration within 2 hours and further administering an additional therapeutic agent. It is noted that the methods of group II do not require an additional therapeutic agent and the methods of group VIII do not have the size limitations of group II, and thus a reference anticipating or rendering obvious group I would not necessarily anticipate or render obvious group VIII.

Inventions III and IV are unrelated. The invention of group III is drawn to methods of delivering therapeutic polysaccharides and the invention of group IV is drawn to a HLGAG

composition with particles having a tap density of greater than 0.4 g/cm^3. It is noted that the methods of group III do not require the specific tap density of group, and thus a reference anticipating or rendering obvious group III would not necessarily anticipate or render obvious group IV.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product can be practiced with another materially different product, such as with the product of group II for example.

Inventions III and VI are unrelated. The invention of group III is drawn to methods of delivering therapeutic polysaccharides and the invention of group VI is drawn to methods of delivering polysaccharides by administering an unformulated glycosaminoglycan and a formulated GAG. It is noted that the methods of group III do not require formulated and unformulated GAG's, and thus a reference anticipating or rendering obvious group III would not necessarily anticipate or render obvious group VI.

Inventions III and VII are unrelated. The invention of group III is drawn to methods of delivering therapeutic polysaccharides and the invention of group VII is drawn to compositions comprising an unformulated HLGAG and a formulated GAG. It is noted that the methods of group III do not require the HLGAG to be formulated or unformulated, and thus a reference anticipating or rendering obvious group III would not necessarily anticipate or render obvious group VII.

Inventions III and VIII are unrelated. The invention of group III is drawn to methods of delivering therapeutic polysaccharides and the invention of group VIII is drawn to methods of delivering HLGAG to produce a peak plasma concentration within 2 hours and further administering an additional therapeutic agent. It is noted that the methods of group III do not require an additional therapeutic agent, and thus a reference anticipating or rendering obvious group I would not necessarily anticipate or render obvious group VIII.

Inventions IV and V are unrelated. Invention IV is drawn to a HLGAG composition with a tap density of 0.4 g/cm^3 and the invention of group V is drawn to a kit comprising HLGAG formulated to release at least 5% of the HLGAG within 2 hours. It is noted that the compositions of group IV do not require the HLGAG to be released at any rate and the kits of group V do not require the particles to be of a specific tap density, and thus a reference anticipating or rendering obvious group IV would not necessarily anticipate or render obvious group V.

Inventions IV and VI are unrelated. Invention IV is drawn to a HLGAG composition with a tap density of 0.4 g/cm^3 and the invention of group VI is drawn to methods of delivering polysaccharides by administering an unformulated glycosaminoglycan and a formulated GAG. It is noted that the compositions of group IV do not require formulated and unformulated GAG's, and the methods of group VI do not require the particles to be of a specific tap density, and thus a reference anticipating or rendering obvious group IV would not necessarily anticipate or render obvious group VI.

Inventions IV and VII are unrelated. Invention IV is drawn to a HLGAG composition with a tap density of 0.4 g/cm^3 and the invention of group VII is drawn to compositions comprising an unformulated HLGAG and a formulated GAG. It is noted that the compositions of

group IV do not require formulated and unformulated GAG's, and the compositions of group VII do not require the particles to be of a specific tap density, and thus a reference anticipating or rendering obvious group IV would not necessarily anticipate or render obvious group VII.

Inventions IV and VIII are unrelated. Invention IV is drawn to a HLGAG composition with a tap density of 0.4 g/cm^3 and the invention of group VIII is drawn to methods of delivering HLGAG to produce a peak plasma concentration within 2 hours and further administering an additional therapeutic agent. It is noted that the compositions of group IV do not require multiple agents, and the methods of group VIII do not require the particles to be of a specific tap density, and thus a reference anticipating or rendering obvious group IV would not necessarily anticipate or render obvious group VIII.

Inventions V and VI are unrelated. The invention of group V is drawn to a kit comprising HLGAG formulated to release at least 5% of the HLGAG within 2 hours and the invention of group VI is drawn to methods of delivering polysaccharides by administering an unformulated glycosaminoglycan and a formulated GAG. It is noted that the kits of group V do not require formulated and unformulated GAG's, and thus a reference anticipating or rendering obvious group IV would not necessarily anticipate or render obvious group VI.

Inventions V and VII are unrelated. The invention of group V is drawn to a kit comprising HLGAG formulated to release at least 5% of the HLGAG within 2 hours and the invention of group VII is drawn to compositions comprising an unformulated HLGAG and a formulated GAG. It is noted that the kits of group V do not require formulated and unformulated GAG's, and thus a reference anticipating or rendering obvious group V would not necessarily anticipate or render obvious group VII.

Inventions V and VIII are unrelated. The invention of group V is drawn to a kit comprising HLGAG formulated to release at least 5% of the HLGAG within 2 hours and the invention of group VIII is drawn to methods of delivering HLGAG to produce a peak plasma concentration within 2 hours and further administering an additional therapeutic agent. It is noted that the kits of group V do not require multiple agents, and thus a reference anticipating or rendering obvious group V would not necessarily anticipate or render obvious group VII.

Inventions VI and VII are unrelated. The invention of group VI is drawn to methods of delivering polysaccharides by administering an unformulated glycosaminoglycan and a formulated GAG and the invention of group VII is drawn to compositions comprising an unformulated HLGAG and a formulated GAG. It is noted that the methods of group VI do not require unformulated HLGAG's, and thus a reference anticipating or rendering obvious group VI would not necessarily anticipate or render obvious group VII.

Inventions VI and VIII are unrelated. The invention of group VI is drawn to methods of delivering polysaccharides by administering an unformulated glycosaminoglycan and a formulated GAG and the invention of group VIII is drawn to methods of delivering HLGAG to produce a peak plasma concentration within 2 hours and further administering an additional therapeutic agent. It is noted that the methods of group VI do not require multiple agents, and thus a reference anticipating or rendering obvious group VI would not necessarily anticipate or render obvious group VIII.

Inventions VII and VIII are unrelated. The invention of group VII is drawn to compositions comprising an unformulated HLGAG and a formulated GAG and the invention of group VIII is drawn to methods of delivering HLGAG to produce a peak plasma concentration

within 2 hours and further administering an additional therapeutic agent. It is noted that the methods of group VII do not require multiple agents and the methods of group VIII do not require an unformulated HLGAG and a formulated GAG, and thus a reference anticipating or rendering obvious group VII would not necessarily anticipate or render obvious group VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Search and examination of multiple compositions and methods of treatment which are not coextensive in scope, and are drawn to divergent products and the use of divergent products, would indeed impose an undue burden upon the examiner in charge of the instant application.

Due to the complexity of the instant restriction requirement, a telephone call was not made to applicants.

It is noted that if applicants elect group I, a further restriction requirement may be imposed to have applicants elect a single disease to be treated from the many they are claiming (i.e. stroke, asthma, cancer, etc.).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
December 23, 2005

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